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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shunji Hayashi

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2100 PENNSYLVANIA AVE. NW

WASHINGTON, DC 20037-3213

EXAMINER

BADR, HAMID R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,497	Applicant(s) HAYASHI ET AL.	
	Examiner HAMID R. BADR	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/26/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment filed on 7/08/2008 is acknowledged.

Claims 6-10 are being considered on the merits.

Objection to Claims

Claims 9-10 are objected to for being dependent on claim 6 inappropriately. Claims 9 and 10 both read "to any one of claims 6". It is clear that the dependency is not appropriately addressed as written. Correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al. (EP 1 112 692 A1, hereinafter R1) in view of Mäyrä-Mäkinen et al. (US 5908646, hereinafter R2)

Regarding Claims 6 and 10

3. R1 teaches the use of *Lactobacillus gasseri*, with a disinfection property against *Helicobacter pylori*, in foods [0001].

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4. R1 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage temperature of 10°C and viable count of more than 10⁷ cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be high. Consequently the limitation of claim 1 regarding the viable counts will depend on how many viable bacteria are initially present. The initial population will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1.

5. R1 explains the use of *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) in foods (Abstract and [0013, 0014, 0015]). Given that this organism is exactly the same as the organism in claim 10, R1 teaches that the claimed organism can be used in foods. R1 discusses the use of *Lactobacillus gasseri* in foods, in food components and in combination with other foods [0017].

6. R1 is silent regarding the incorporation of *L. gasseri* in cheese.

7. The incorporation of lactobacilli, for their antagonistic properties into cheese, is explored by R2. R2 discloses an anticlostridial *Lactobacillus rhamnosus*, which can be used to prevent problems caused by clostridia in a number of different fields (Col. 5, lines 39-42) including the protection of food. R2 further mentions that it is possible to employ strains of *Lactobacillus rhamnosus* for medical purposes (Col. 5, lines 47-48). Incorporation of lactobacilli into Swiss and Edam cheeses is discussed in detail

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(Example 3 and 4). Growing the lactobacillus species (LC 705) at 37°C for 24 hours and the population of organisms grown (5×10^8 /ml) are taught in Example 3.

8. The cheese making process is well known in the art. Further more since yeast extract is used for the culture of Lactobacilli, the culture of Lactobacilli being added to the milk before the formation of the curd will always carry some yeast extract with it. Furthermore, in the cheese making industry, the addition of any starter culture will take place before the formation of a curd. The incubation of the molded and pressed cheese is also a known practice in the industry. For example, in cheddar cheese making, after the cheddaring process, the cheese is molded and pressed to form big blocks of cheese which is incubated and aged as such. As a result the limitations of claim 6, regarding the cheese making process, are all known in the industry.

Regarding Claim 7

9. Incubation of the molded and pressed curd will be an extension of the incubation period for a starter culture. This is performed in order to increase the number of viable bacteria in the curd. Incubating the curd without cooling it will allow the *Lactobacilli* to proliferate more and increase in number.

Regarding Claim 8

10. *Lactobacillus gasseri* is a mesophilic organism. R1 demonstrates that growth is impaired at 15°C (page 3, B-Physiological properties). It is obvious to incubate a microorganism in a range suitable for growth and proliferation. Incubation of an organism in a medium for growth and proliferation is normally done for 24 hours. The incubation time limitation of claim 8 is a usual incubation time known in the art.

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Regarding Claim 9

11. The lactobacilli starter cultures in the cheese industry may be added to the raw milk.

12. It is clear that the addition of starter culture and *L. gasseri* to the liquid milk will start the fermentation process and this fermentation process will continue after molding and incubating the cheese.

13. It would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the teachings of R1 and incorporate the anti-helicobacter *L. gasseri* of R1, which can be grown in a food, into cheese as taught by R2. One would have done so to benefit from a more shelf stable product such as cheese as compared to yogurt taught by R1. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success in making a cheese containing *L. gasseri*.

14. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al. (EP 1 112 692 A1, hereinafter R1) in view of Germond et al. (WO 0188150, hereinafter R3).

Regarding Claims 6 and 10

15. R1 teaches the use of *Lactobacillus gasseri*, with a disinfection property against *Helicobacter pylori*, in foods [0001].

16. R1 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage

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temperature of 10°C and viable count of 10⁷ cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be high. Consequently the limitation of claim 1 regarding the viable counts will depend on how many viable bacteria are initially present. The initial population will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1. R1 explains the use of *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) in foods (Abstract and [0013, 0014, 0015]). Given that this organism is exactly the same as the organism in claim 3, R1 teaches that the claimed organism can be used in foods. R1 discusses the use of *Lactobacillus gasseri* in foods, in food components and in combination with other foods [0017].

17. R1 is silent regarding the incorporation of *L. gasseri* in cheese.

18. R3 discloses the incorporation of *L. gasseri* in dairy products including cheese. R1 claims *Lactobacillus gasseri* as one of the lactic acid bacteria (claim 2) which can be added to a food product (claim 7) and the food product include cheese, yogurt, fermented milks, ice cream (claims 8-9).

19. The cheese making process is well known in the art. Further more since yeast extract is used for the culture of *Lactobacilli*, the culture of *Lactobacilli* being added to the milk before the formation of the curd will always carry some yeast extract with it. Furthermore, in the cheese making industry, the addition of any starter culture will take place before the formation of a curd. The incubation of the molded and pressed cheese

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is also a known practice in the industry. For example, in cheddar cheese making, after the cheddaring process, the cheese is molded and pressed to form big blocks of cheese which is incubated and aged as such. As a result the limitations of claim 6 are all known in the industry.

Regarding Claim 7

20. Incubation of the molded and pressed curd will be an extension of the incubation period for a starter culture. This is performed in order to increase the number of viable bacteria in the curd. Incubating the curd without cooling it will allow the *Lactobacilli* to proliferate more and increase in number.

Regarding Claim 8

21. *Lactobacillus gasseri* is a mesophilic organism. R1 demonstrates that growth is impaired at 15°C (page 3, B-Physiological properties). It is obvious to incubate a microorganism in a range suitable for growth and proliferation. Incubation of an organism in a medium for growth and proliferation is normally done for 24 hours. The incubation time limitation of claim 8 is a usual incubation time known in the art.

Regarding Claim 9

22. The lactobacilli starter cultures in the cheese industry may be added to the raw milk.

23. It is clear that the addition of starter culture and *L. gasseri* to the liquid milk will start the fermentation process and this fermentation process will continue after molding and incubating the cheese.

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24. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 and incorporate the organism into cheese as taught by R3. One would have done so to make a cheese containing *L. gasseri* and a longer shelf life as offered by cheese. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making a cheese containing *L. gasseri*.

Response to Arguments

Applicants' arguments have been fully considered. Based on the following reasons, those arguments are not deemed persuasive.

A. Applicants state that claims 9-10 have been amended to remove multiple dependency and to depend directly from claim 6.

a. Both claims 9 and 10 read "to any one of claims 6". This is inappropriate. See claim objections above.

B. Applicants admit that *L. gasseri* has disinfection property against *H. pylori* according to Kimura. Applicants also admit that Lactobacilli can be incorporated into cheese according to Mayra-Makinen. However, Applicants argue that these references do not teach adding yeast extract to the milk before formation of curd.

a. Those of skill in the cheese making art know that the starter culture is added to the milk before adding the enzyme for curd formation. Any other addition should also be carried out before the addition enzyme for the formation of curd. Yeast extract is either contained in the starter culture or can be added. The reserve starter cultures always have yeast extract to support growth. However, what is important is that *L. gasseri* can

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be used against *H. pylori*, and that *L. gasseri* can be incorporate into cheese. Both of these concepts are taught by the cited references.

b. Applicants also argue that their cheese sustains high bacterial counts.

However, it is noted that this concept of sustaining high bacteria counts is being taught by Kimura. Their yogurt sustains 10^7 cfu/ml. Therefore, the cheese is expected to sustain high counts as presently claimed.

C. While Mayra Makinen (R2) discloses the use of *L. rhamnosus* in cheese, it does not claim the anti-helicobacter property. R2 is only teaching that Lactobacilli can be incorporated into cheese regardless of their function and this is what is needed to make the invention of the present application. Two elements are known: *Lactobacillus gasseri* is anti-helicobacter and *Lactobacilli* may be incorporated in cheese. Thus, it would have been obvious to one of ordinary skill in the art to incorporate the *L. gasseri* from R1 into cheese. Applicants' argument that *L. rhamnosus* and *L. gasseri* are different organisms is true. However, if *L. rhamnosus* can be used for an antagonistic property and can be delivered by cheese, it is obvious to those of skill in the art that *L. gasseri* can be used for its antagonistic properties and can be delivered in cheese as well.

D. The shelf life of the cheese having viable organisms is important. However, adding an organism to the cheese and storing it at 10C for six months and finding the survival rate would be only a test. Any other Lactobacilli would probably do the same thing as long as the environment in the cheese is appropriate especially regarding the oxygen toxicity and the water activity of the cheese.

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E. The teachings of R3 are further proof that *L. gasseri* can be incorporated into cheese. Since the *L. gasseri* is being used as a probiotic in R3, the viable organisms at certain counts per gram of cheese would be inherent in the teachings of R3.

F. R1 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage temperature of 10°C and viable count of 10⁷ cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be high. Consequently the limitation of claim 6 regarding the viable counts will depend on how many viable bacteria are initially present. The initial population will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794